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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,740	06/23/2000	Markus Pompejus	BGI-121CP	4954

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EXAMINER
FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
1652	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/606,740	Applicant(s) Pompejus et al.
	Examiner Christian L. Fronda	Art Unit 1652

-- ***The MAILING DATE of this communication appears on the cover sh et with th correspondence address*** --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-38 is/are pending in the application.

4a) Of the above, claim(s) 18-38 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-17 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicants' election without traverse of Group I in Paper No. 11 is acknowledged. Applicants' election with traverse of SEQ ID NO: 1 in Paper No.11 is acknowledged. The traversal is on the grounds that ten sequences is a reasonable number of sequence to be examined in a single application and that searches for each SEQ ID NO: would be coextensive.

This is not found persuasive because each nucleotide sequence encodes patentable distinct, independent, and unrelated proteins (see Table 1 of the disclosure). Thus, a search of all the SEQ ID NOS: in the patent literature and the non-patent literature cannot be made without serious burden because each SEQ ID NO requires separate searches that have different limits, boundaries, scope, and subject matter. Because these inventions are distinct for the reasons given above and of record and have acquired a separate status in the art as shown by their divergent subject matter, restriction for examination purposes is proper.

The requirement is still deemed proper and is therefore made FINAL. Upon further consideration a nucleic acid molecule encoding SEQ ID NO: 2 will also be examined.

2. Claims 1-17, SEQ ID NO: 1, and SEQ ID NO: 2 are under consideration in this Office Action.

Claim Objections

3. Claim 2 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 U.S.C. § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-17 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

The specification discloses the nucleotide sequence of SEQ ID NO: 1 and the deduced amino acid sequence of SEQ ID NO: 2 and assigns the protein encoded as a diaminopimelate epimerase (Table 1). The specification does not show any enzyme assays to demonstrate that the encoded protein has a diaminopimelate epimerase activity.

The state of the art as exemplified by Attwood et al. (Comput. Chem. 2001, Vol. 25(4), pp. 329-39) is such that "...we do not fully understand the rules of protein folding, so we cannot predict protein structure; and we cannot invariably diagnose protein function, given knowledge only of its sequence or structure in isolation" (see Abstract and entire publication). Furthermore, Ponting (Brief. Bioinform. March 2001, Vol. 2(1), pp. 19-29) states that "...predicting function by homology is a qualitative, rather than quantitative, process and requires particular care to be taken...due attention should be paid to all available clues to function, including orthologue identification, conservation of particular residue types, and the co-occurrence of domains in proteins" (See Abstract and entire publication).

The specification does not specifically disclose the specific function of the protein of SEQ ID NO: 2. It appears that the main utility of the nucleic acid and protein is to carry out further research to identify the biological function and substantial utilities associated with the protein. Substantial utility defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utility. Thus, the claimed invention has no specific or substantial asserted utility.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above in the rejection of claims 1-17 under 35 U.S.C. 101, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore claim 6 which encompasses any nucleic acid molecule comprising a nucleotide sequence which has at least 50% identity to SEQ ID NO: 1 or complement thereof is not enabled by the specification. Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount

of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The state of the art as exemplified by Attwood et al. (Comput. Chem. 2001, Vol. 25(4), pp. 329-39) is such that "...we do not fully understand the rules of protein folding, so we cannot predict protein structure; and we cannot invariably diagnose protein function, given knowledge only of its sequence or structure in isolation" (see Abstract and entire publication). Furthermore, Ponting (Brief. Bioinform. March 2001, Vol. 2(1), pp. 19-29) states that "...predicting function by homology is a qualitative, rather than quantitative, process and requires particular care to be taken...due attention should be paid to all available clues to function, including orthologue identification, conservation of particular residue types, and the co-occurrence of domains in proteins" (See Abstract and entire publication).

The specification provides guidance a nucleic acid molecule consisting of the nucleotide sequence of SEQ ID NO: 1 or a nucleic acid molecule encoding a protein consisting of the amino acid seqeunce of SEQ ID NO: 2. While molecular biological techniques and genetic manipulation are known in the prior art and the skill of the artisan are well developed, knowledge regarding the nucleotides to change, i.e. delete, insert, substitute, and combinations thereof, to make a nucleic acid molecule having at least 50% identity to SEQ ID NO: 1 is lacking. Furthermore, knowledge regarding the biological function of a nucleic acid molecule having at least 50% identity to SEQ ID NO: 1 is lacking.

Thus, searching for specific nucleotides to change to make the claimed nucleic acid is well outside the realm of routine experimentation and predictability in the art of success is extremely low. Also well outside the realm of experimentation is identifying the function and use of the nucleic acid molecule having at least 50% identity to SEQ ID NO: 1.

The amount of experimentation to determine what specific nucleotides to change to make the claimed nucleic acid molecule and determining the biological function and utility of the claimed nucleic acid molecule is enormous. Such experimentation entails selecting specific nucleotides to change, i.e. delete, insert, substitute, and combinations thereof, to make a nucleic acid molecule having at least 50% identity to SEQ ID NO: 1 and determining the biological function and utility of the nucleic acid.

Since routine experimentation in the art does not include such enormous experimentation, where the expectation of determining the biological function of a nucleic acid molecule having at least 50% identity to SEQ ID NO: 1 is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific nucleotides to change and the biological function and utility of the nucleic acid molecule. Without such a guidance, the experimentation left to those skilled in the art is undue.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 2, 8, 15, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 2, the recited limitations are vague and indefinite because the specific identity and function of the claimed proteins are not known and not recited. Furthermore, there is insufficient antecedent basis for the limitations cited in lines 3-4.

Claim 8 is indefinite because the specific hybridization are not recited and one of skill in the art cannot determine the metes and bounds of the claimed invention.

Claims 15 and 16 are vague and indefininte because the meaning of the phrase "modulation in production of a fine chemcial" is not known and the specific identity of the fine chemical is not known and not recited in claims 15 and 16.

Claim Rejections - 35 U.S.C. § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States..

11. Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Cole et al (Accession Z98209 AL123456).

Cole et al (Accession Z98209 AL123456) teach a nucleic acid molecule comprising a fragment of at least 15 nucleotides of the nucleotide sequence of SEQ ID NO: 1 (see attached alignment). Thus, the reference teaching anticipate the claimed invention.

12. Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Smith (Accession U00019).

Smith (Accession U00019) teach a nucleic acid molecule which is expected to hybridize to the nucleic acid of SEQ ID NO: 1 since the claim does not recite the specific hybridization

conditions (see alignment).

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. The Examiner can be contacted Monday-Friday from 8:30AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF

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